HIGH PRODUCTION VOLUME (HPV) CHEMICAL CHALLENGE PROGRAM

FINAL SUBMITTAL

For

2, 4, 8, 10-Tetraoxa-3,9-diphosphaspiro[5.5]undecane, 3,9-bis(octadecyloxy)-

CAS No. 3806-34-6

Submitted to the US EPA

by

Chemtura (formerly Crompton) Corporation

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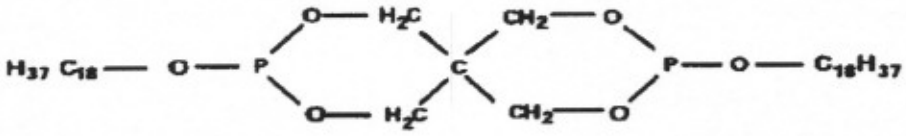
Test Plan for Weston 618

1. General Information

1.1 CAS Number: 3806-34-6

1.2 Molecular Weight: 733.06

1.3 Structure and formula: $C_{41}H_{82}O_6P_2$



1.4 Introduction

2,4,8,10-Tetraoxa-3,9diphosphaspiro[5.5]undecane, 3,9-bis(octadecyloxy)- (Weston 618) is used as a color and molecular weight stabilizer for polyolefms, polyesters, elastomers, styrenics, engineering thermoplastics and adhesive formulations.

2. Review of Existing Data and Development of Test Plan

Chemtura Corporation has undertaken a comprehensive evaluation of all relevant data on the SIDS endpoints of concern for Weston 618.

The availability of the data on the specific SIDS endpoints is summarized in Table 1.

Table 1: Available adequate data for Weston 618

CAS NO. 3806-34-6	Information Available?	GLP	OECD Study?	Other Study?	Estimation Method?	Acceptable?	SIDS Testing Required?
	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N
Physicochemical							
Melting Point	Y	N					N
Boiling Point	Y				Y	Y	N
Vapour Pressure	Y				Y	Y	N
Water Solubility	Y	Y			Y	Y	N
Partition Coefficient (Kow)	Y				Y	Y	N
Environmental Fate							
Biodegradation	Y				Y	Y	N
Hydrolysis	N						N
Photodegradation	Y				Y	Y	N

Transport and Distribution between Environmental Compartments	Y				Y	Y	N
Ecotoxicology							
Acute Fish	Y				Y	Y	N
Acute Daphnia	Y				Y	Y	N
Acute Algae	Y				Y	Y	N
Toxicology							
Acute Oral	Y	N	N			Y	N
Repeat Dose toxicity	Y	N	N			Y	N
Genetic toxicity – Gene mutation	Y	N				Y	N
Genetic toxicity – Chromosome Aberration	Y	Y	Y			Y	N
Reproductive toxicity	Y	Y	Y			Y	N
Developmental toxicity/teratogenicity	Y	Y	Y			Y	N

A. Evaluation of Physiochemical Data

1. Melting Point

   The melting point was reported to be between 37 - 46°C on a manufacturer's MSDS.

2. Boiling Point

   The boiling point was estimated to be 705°C using MPBPWIN v 1.40.

3. Vapour Pressure

   The vapor pressure was estimated to be 1.06×10^{-18} hPa at 25°C using MPBPWIN v 1.40.

4. Water Solubility

   The water solubility could not be experimentally determined because the test substance is hydrolytically unstable. The water solubility is estimated to be 2.95×10^{-12} mg/L at 25°C using WSKOW v 1.40.

5. Partition Coefficient

   The log Pow is estimated to be 15 using KOWWIN v 1.66.

Summary of Physicochemical Properties Testing: Existing data for melting point, boiling point, vapor pressure, partition coefficient and water solubility are considered to fill these endpoints adequately.

B. Evaluation of Environmental Fate Data

1. Biodegradation

The biodegradability of the chemical has been estimated using Biowin v4.00 and the results indicate the chemical to not be readily biodegradable. The chemical contains no biodegradable groups.

2. Hydrolysis

A GLP study was conducted on the test substance in water, and it was determined that due to the poor solubility and hydrolytically unstable as determined during the water solubility testing, a half-life could not be determined. The Fugacity model calculated half-life was 1.44e003 hr.

The test substance is hydrolytically unstable as determined during the water solubility testing.

3. Photodegradation

The potential for photodegradation of Weston 618 has been estimated using the AOPWIN v1.90, and indicated atmospheric oxidation via OH radicals reaction with a half-life of 0.689 hours.

4. Transport and Distribution between Environmental Compartments

An Epiwin Level III Fugacity Model calculation has been conducted and indicates distribution mainly to sediment and, to a lesser extent, soil for emissions of 1000 kg/hr simultaneously to air water and soil compartments.

Summary of Environmental Fate Testing: Existing data for photodegradation, hydrolysis, biodegradation and transport and distribution between environmental compartments are considered to fill these endpoints adequately.

C. Evaluation of Ecotoxicity Data

1. Acute Toxicity to Fish

The LC_{50} (96 h) was estimated to be 2.94×10^{-10} mg/L using ECOSAR v 0.99g. This is greater than the estimated limit of solubility of the substance.

2. Acute Toxicity to Daphnia

The EC_{50} (48 h) was estimated to be 7.76×10^{-10} mg/L using ECOSAR v 0.99g.

This is greater than the estimated limit of solubility of the substance.

3. Acute Toxicity to Algae

The EC_{50} (96 h) was estimated to be $1.03x10^{-9}$ mg/L using ECOSAR v 0.99g. This is greater than the estimated limit of solubility of the substance.

Summary of Ecotoxicity Testing: Weston 618 is estimated to be toxic to the environment only at levels above its limit of solubility.

D. Evaluation of Human Health Effects Data

1. Acute Oral Toxicity

The acute oral toxicity of Weston 618 is reported as LD_{50} > 10000 mg/kg in a rat study. None of the animals showed any signs of toxicity at the maximum dose.

2. Acute Dermal Toxicity (non-SIDS endpoint)

Acute dermal toxicity was reported as LD_{50} > 2000 mg/kg using rabbits in an OECD 402 study conducted to GLP.

3. Eye Irritation (non-SIDS endpoint)

Weston 618 was found to be non-irritating to rabbit eyes.

4. Repeat Dose Toxicity

In a 90-day oral feed study conducted using rats, the observed NOAEL was > 3000 ppm. There were no significant differences between controls and the dose groups in any of the parameters studied.

In a 7 day range finding experiment, there were no clinical signs, no deaths, no differences in body weights or food intake, no treatment related organ weight changes or gross pathological changes in groups of rats exposed to 100, 400 and 1000 mg/kg bw/d.

5. Genotoxicity

Weston 618 tested negative in an Ames test using *Salmonella typhimurium* strains TA97, TA98, TA l00 and TA102 and Escherichia coli strain WP2 (PKM l01) with and without metabolic activation.

In an in vivo mouse micronucleus assay (OECD 474) no genotoxic effects were observed at doses up to 2000 mg/kg (the maximum dose tested).

6. Reproductive and Developmental Toxicity
There were no effects on fertility, developmental toxicity or teratogenicity in rats exposed to 1000 mg/kg bw/d (the highest dose tested) in an OECD TG 421 study.

Summary of Human Health Effects Testing: All endpoints are considered to have been filled adequately.

3. Evaluation of Data for Quality and Acceptability

The collected data were reviewed for quality and acceptability following the general US EPA guidance [2] and the systematic approach described by Klimisch et al [3]. These methods include consideration of the reliability, relevance and adequacy of the data in evaluating their usefulness for hazard assessment purposes. This scoring system was only applied to ecotoxicology and human health endpoint studies per EPA recommendation [4]. The codification described by Klimisch specifies four categories of reliability for describing data adequacy. These are:

(1) Reliable without restriction: Includes studies or data complying with Good Laboratory Practice (GLP) procedures, or with valid and/or internationally accepted testing guidelines, or in which the test parameters are documented and comparable to these guidelines.

(2) Reliable with Restrictions: Includes studies or data in which test parameters are documented but vary slightly from testing guidelines.

(3) Not Reliable: Includes studies or data in which there are interferences, or that use non-relevant organisms or exposure routes, or which were carried out using unacceptable methods, or where documentation is insufficient.

(4) Not Assignable: Includes studies or data in which insufficient detail is reported to assign a rating, e.g. listed in abstracts or secondary literature.

4. Conclusion

Chemtura Corporation has met its commitment for the sponsorship of 2,4,8,10-Tetraoxa-3,9diphosphaspiro[5.5]undecane, 3,9-bis(octadecyloxy)- (Weston 618) under the US EPA HPV Challenge Program.

5. References

[1] US EPA, EPI Suite Software, 2000

[2] USEPA (1998). Guidance for Meeting the SIDS Requirements (The SIDS Guide). Guidance for the HPV Challenge Program. Dated 1 l/2/98.

[3] Klimisch, H.-J., et al (1997). A Systematic Approach for Evaluating the Quality of Experimental Toxicological and Ecotoxicological Data. Regul. Toxicol. Pharmacol. 25: l-5

[4] USEPA (1999). Determining the Adequacy of Existing Data. Guidance for the HPV Challenge Program. Draft dated 2/10/99.